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| EXAMINER | |
|---|---|
| TRAN, MY CHAU T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/848,727 | GAU, VINCENT JEN-JR. | |
| | Examiner | Art Unit | |
| | MY-CHAU T TRAN | 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *83-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *83-113* is/are rejected.

7)☒ Claim(s) *96-97, and 107-108* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

1. Applicant's amendment filed 6/28/2004 is acknowledged and entered. Claims 1-20, and 51-52 have been canceled. Claims 83-113 have been added.

2. Claims 53-74 were canceled and Claims 75-82 were added by the amendment filed on 11/13/2003.

3. Claims 21-50 were canceled and Claims 51-74 were added by the amendment filed on 5/5/2003.

4. Claims 83-113 are pending.

### *Election/Restrictions*

5. Claims 53-74, filed on 5/5/2003, are withdrawn from consideration as being directed to a non-elected invention since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Claims 21-50 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to ***nonelected inventions***, there being no allowable generic or linking claim. The election was made **without** traverse in the reply filed on 11/13/02 because applicant did not

distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Priority***

7. This application claims priority to a provisional application 60/201,603 filed 5/3/2000.

***Withdrawn Rejections***

8. The rejection of claim 75 under 35 USC 112, first paragraph (new matter rejection) has been withdrawn in light of applicant indication where support can be found, i.e. paragraph 76 and 77, and cancellation of claim 75. Additionally, it is noted applicant has indicated that new claim 102 is the 'duplicate' of cancelled claim 75. However, it is new claim 101 that is the 'duplicate' of cancelled claim 75. If applicant disagrees, applicant should present a detailed analysis as to why the new claim 102 is the 'duplicate' of cancelled claim 75.

9. The rejection of claim 77 under 35 USC 112, first paragraph (new matter rejection) has been withdrawn in light of applicant's cancellation of claim 77. Additionally, it is noted applicant has indicated that new claim 103 is the 'duplicate' of cancelled claim 77. However, it is new claim 102 that is the 'duplicate' of cancelled claim 77. If applicant disagrees, applicant should present a detailed analysis as to why the new claim 103 is the 'duplicate' of cancelled claim 77. Furthermore, this rejection is still applicable to the new claim 102 (see New Rejection – Necessitated by Amendment below regarding this rejection for claim 102), and applicant argument with regard to support is address below in Response to Arguments.

10. The rejection of claim 80 under 35 USC 112, first paragraph (new matter rejection) has been withdrawn in light of applicant's cancellation of claim 80.

11. The rejection of claims 1-13, 15-18, 20, 51-52, 75-76, and 78-79 under 35 USC 102(b) as being anticipated by Song et al. (US Patent 5,567,302) has been withdrawn in light of applicant cancellation of claims 1-13, 15-18, 20, 51-52, 75-76, and 78-79. Additionally, applicant's arguments with regard to Song et al. (US Patent 5,567,302) in view of the new claim 83 is considered and address below in Response to Arguments.

12. The rejection of claims 1-9, 11-13, 15-18, 20, 51-52, 75-76, and 78-82 under 35 USC 102(b) as being anticipated by Heller et al. (US Patent 5,632,957) has been withdrawn in view of applicant cancellation of claims 1-9, 11-13, 15-18, 20, 51-52, 75-76, and 78-82. Additionally, applicant's arguments with regard to Heller et al. (US Patent 5,632,957) in view of the new claim 83 is considered and address below in Response to Arguments.

13. The rejection of claims 1-8, 11-13, 15-17, 20, 51-52, and 75-82 under 35 USC 102(e) as being anticipated by Heller et al. (US Patent 6,238,624 B1; *filing date 10/4/1996*) has been withdrawn has been withdrawn in view of applicant cancellation of claims 1-8, 11-13, 15-17, 20, 51-52, and 75-82, and applicant's arguments are considered but are moot in view of the new ground(s) of rejection.

14. The rejection of claims 1-20, 51-52, and 75-82 under 35 USC 103(a) as being obvious over Song et al. (US Patent 5,567,302) and Han et al. (US Patent 6,268,161 B1) has been withdrawn in view of applicant cancellation of claims 1-20, 51-52, and 75-82.

15. The rejection of claims 1-9, 11-20, 51-52, and 75-82 under 35 USC 103(a) as being obvious over Heller et al. (US Patent 5,632,957) and Han et al. (US Patent 6,268,161 B1) has been withdrawn in light of applicant cancellation of claims 1-9, 11-20, 51-52, and 75-82.

16. Claims 83-113 are treated on the merit in this Office Action.

***New Rejections – Necessitated by Amendment***

***Claim Objections***

17. Claim 96 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 89. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

18. Claim 97 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 90. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim

to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

19. Claim 108 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 106. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

20. Claim 107 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 107 recite "*The method of claim 107*", i.e. it is dependent on itself.

***Claim Rejections - 35 USC § 112***

21. Claims 83-113 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The new claim 83 added the method step of "*controlling a potential difference between two of the electrodes*". The new claims 106 and 108 recite the limitation of applying "*a current through a third of the electrodes*". The new claim 106 recites the limitation of applying "*a current through a counter electrode*" to control the potential difference between a reference electrode and a working electrode. The new claim 111 recites the limitation of "*the electrical signal is measured while the potential difference is controlled*". Applicant has not pointed to support for these added limitations and the examiner deems that it is not supported by the specification as filed. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure.

22. Claim 102 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The new claim 102 limitation of "*each of the electrodes has a different shape*". Applicant has not pointed to support for these added limitations and the examiner deems that it is not supported by the specification as filed {*see Response to Arguments below regarding the support referred to in the arguments filed 6/28/2004*}. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure.

23. Claim 107 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The new claim 107 recites the limitation that "*the counter electrode and the reference electrode are each separated from the working electrode by 200μm to 220μm*". Applicant has not pointed to support for this added limitation and the examiner deems that it is not supported by the specification as filed. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure.

24. Claim 113 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The new claim 113 recites the limitation that "*the sensor occupies an area of 160μm$^2$ to 25mm$^2$*". Applicant has not pointed to support for this added limitation and the examiner deems that it is not supported by the specification as filed. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure.

25. Claims 83-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The method step of "measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent" of claim 83 is vague and indefinite because it is unclear as to the manner in which the measured electrical signal from the biosensor correlates with the detection of the target analyte in the sample reagent, i.e. it is unclear as to the relationship between the signal produced from the electrodes and the target analyte in the sample reagent.

b. The method step of "controlling a potential difference between two of the electrodes" of claim 83 is vague and indefinite because there is a gap between this method step and the claimed method of detecting the presence or measuring the quantity of the target analyte in the sample reagent, i.e. it is unclear as to the correlation between the method step of controlling the electrodes and the method step of detecting the target analyte in the sample reagent. Thus the claimed method is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

c. Claim 102 recites the limitation "electrodes" in line 1. There is insufficient antecedent basis for this limitation in the claim 91 since the limitation of claim 91 refers to the type of adhesive.

d. Claim 104 recites the limitation "contacting the microfabricated electrochemical biosensor" in line 1. There is insufficient antecedent basis for this limitation in the claim

83 since claim 83 does not recite a contacting step. Furthermore, the phrase "microfabricated electrochemical" lacks antecedent basis in the claim 83.

e. Claim 106 is vague and indefinite because it is unclear what "includes" refers to, i.e. the reference and working electrodes refer to the 'two electrodes' and the counter electrode refers to the third electrode of the claimed controlling step. It is suggested that applicant amend the claim by replacing "*includes controlling the potential difference between a reference electrode and a working electrode by application of a current through a counter electrode,*" with "wherein controlling the potential difference is between a reference electrode and a working electrode, and the application of a current is through a counter electrode; and".

f. Claim 106 recites the limitation "a third of the electrodes" in line 2. There is insufficient antecedent basis for this limitation in the claim 83 since this limitation can be interpreted as an electrode being section into three parts, i.e. 1/3 of the electrodes. It is suggested that applicant amend the claim by replacing "*a third of the electrodes*" with " a third electrode".

g. Claim 108 recites the limitation "a third one of the electrodes" in line 2. There is insufficient antecedent basis for this limitation in the claim 83 since this limitation can be interpreted as an electrode being section into three parts, i.e. 1/3 of the electrodes. It is suggested that applicant amend the claim by replacing "*a third one of the electrodes*" with " a third electrode".

h. Claim 111 is vague and indefinite because it is unclear as to the manner in which the measured electrical signal from the biosensor correlates with the detection of the

target analyte in the sample reagent, i.e. it is unclear as to the relationship between the signal produced from the electrodes and the target analyte in the sample reagent since the measured signal can be interpreted as the 'bias potential' of the electrodes. Thus the claimed method is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

***Claim Rejections - 35 USC § 102***

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

27. Claims 83-94, 96-101, 103, 108-110, and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (US Patent 5,567,302).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Song et al. disclose an analytical system and method for detecting biochemical agents that catalyze a redox potential change (see e.g. Abstract; col. 1, lines 8-10; col. 2, lines 41-58). The method comprises the step of 1) electrochemically contacting the electrolyte containing the biochemical agent (target analyte) with the electrodes, which is in a microvolume chamber (refers to the instant claimed positioning step) (see e.g. claim 1(a); col. 8, line 51 to col. 9, line 21; col. 15, lines 10-14); and 2) measuring the change in the potential of the electrolyte (refers to the instant claimed measuring step) (see e.g. claim 1(b); col. 2, lines 50-51; col. 8, lines 16-48; col. 15, lines 10-14). The method of Song et al. further discloses the claimed method step of controlling a potential difference between two of the electrodes (see e.g. col. 5, lines 53-56; col. 17, lines 21-52). The analytical system comprises a small volume detection chamber (refers to the claimed well structure) (see e.g. col. 1, lines 31-32; col. 17, lines 31-33; fig. 1, ref. #81-88), and an electrode array with eight electrodes sites (see e.g. col. 5, line 67 to col. 6, line 10). The electrode array comprises of a silicon wafer (refers to the claimed substrate) (see e.g. col. 15, line 61), gold electrodes (refers to the claimed single layer of conductive material), chromium as the adhesion layer (see e.g. col. 16, line 30-42), and electrode leads (see e.g. col. 6, lines 7-9). The electrode Therefore, the analytical system and method of Song et al. anticipate the presently claimed invention.

28. Claims 83-91, 93-94, 96-101, 103-105, 108-109 and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Heller et al. (US Patent 5,632,957).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the*

*electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Heller et al. disclose a self-addressable self-assembling microelectronic device that can carry out a variety of reactions in microformats (see e.g. Abstract; col. 4, lines 48-59; col. 5, lines 3-37). The reaction steps comprise transporting the analytes to specific location wherein the analytes are effectively concentrated and reacted with the specific binding entity at the microlocation (refers to the instant claimed positioning step) (see e.g. col. 5, lines 4-8; col. 8, lines 18-25), and detecting the analyte by the detectable signal (refers to the instant claimed measuring step) (see e.g. col. 5, lines 32-37; col.9, lines 5-28; col. 19, lines 15-41). The method of Heller et al. further discloses the claimed method step of controlling a potential difference between two of the electrodes (see e.g. col. 7, lines 3-11; col. 8, line 53 to line 9; col. 9, lines 21-28). The microelectronic device comprises a substrate supporting an array of electronically addressable microlocations (see e.g. col. 7, line 66 to col. 8, lines 4; fig. 2A) and contact pads (refers to instant claim 100) (see e.g. col. 9, lines 52-64; fig. 3). The microlocations comprise an electrode layer, a permeation layer, and an attachment layer (see e.g. col. 8, lines 1-17; fig. 2). The electrode layer comprises a metal layer such as gold (refers to the claimed single layer of conductive material) and an adhesive layer such as titanium between the metal layer and the silicon substrate (see e.g. col. 16, lines 30-41; col. 17, lines 11-21). The microlocations further discloses the claimed positioning of the electrodes of claim 105 wherein two of the electrodes extend about a periphery of another of the electrodes (see e.g. fig. 2B, and 3). Therefore the microelectronic device and method of Heller et al. anticipate the presently claimed invention.

29. Claims 83-94, 96-97, 99-101, 103, 106, and 108-112 are rejected under 35 U.S.C. 102(e) as being anticipated by Buck, Jr. et al. (US Patent 6,294,062 B1; *filing date of 6/1/1998*).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Buck, Jr. et al. teaches immunosensors based on direct electrochemical measurement of detectable species with microarray electrodes under bipotentiostatic control and the method of detecting biological analytes in a liquid sample using the immunosenors (see e.g. Abstract; col. 1, lines 60-62; col. 3, lines 43-61; col. 4, lines 11-24). The method comprises the claimed step of 1) positioning the sample reagent on a biosensor (see e.g. col. 4, lines 27-31; col. 6, lines 49-53); 2) controlling a potential difference between two of the electrodes (see e.g. col. 4, lines 35-41; col. 6, lines 59-67; col. 7, lines 3-10); 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent (see e.g. col. 4, lines 41-50; col. 7, lines 1-2, and 11-15). The method of Buck, Jr. et al. further discloses the instant claimed method step of controlling the potential difference is between the reference electrode and the working electrode, and the application of the current is through the counter electrode (see e.g. col. 8, lines 51-61). The liquid sample is a biological fluid (refers to instant claims 85-86 and 103) (see e.g. col. 7, lines 27-36). The immunosensors comprises the electrode structure that includes a reference electrode, working electrode and an auxiliary electrode for current control (refers to instant claimed biosensor and instant claims 108-111) (see e.g. col. 43-

61; col. 7, lines 65-66; col. 8, line 54-55). The electrode is on a silicon substrate with a layer of chromium, and comprise of gold (refers to instant claims 84, 87-92, 94, 96-97, 99, 101, and 112) (see e.g. col., lines 26-40). The electrode structure is formed on an inner surface of a chamber for receiving the liquid sample (refers to instant claim 93) (see e.g. col. 8, lines 41-45). The electrode structure also is in contact with conductors (refers to claim 100) (see e.g. col. 49-50). Thus the immunosensors and method of Buck, Jr. et al. anticipate the presently claimed invention.

***Claim Rejections - 35 USC § 103***

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

31. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

32. Claims 83-104, and 106-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (US Patent 5,567,302) and Han et al. (US Patent 6,268,161 B1).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Song et al. disclose an analytical system and method for detecting biochemical agents that catalyze a redox potential change (see e.g. Abstract; col. 1, lines 8-10; col. 2, lines 41-58). The method comprises the step of 1) electrochemically contacting the electrolyte containing the biochemical agent (target analyte) with the electrodes, which is in a microvolume chamber (see e.g. claim 1(a); col. 8, line 51 to col. 9, line 21; col. 15, lines 10-14) (refers to the instant claimed positioning step); and 2) measuring the change in the potential of the electrolyte (see e.g. claim 1(b); col. 2, lines 50-51; col. 8, lines 16-48; col. 15, lines 10-14) (refers to the instant claimed measuring step). The method of Song et al. further discloses the claimed method step of controlling a potential difference between two of the electrodes (see e.g. col. 5, lines 53-56; col. 17, lines 21-52). The analytical system comprises a small volume detection chamber (well) (col. 1, lines 31-32; col. 17, lines 31-33; fig. 1, ref. #81-88), and an electrode array with eight electrodes sites (col. 5, line 67 to col. 6, line 10). The electrode array comprises of a silicon wafer (refers to the claimed substrate) (col. 15, line 61), gold electrodes (refers to the claimed single layer of conductive material), chromium as the adhesion layer (col. 16, line 30-42), and electrode leads (col. 6, lines 7-9).

The method of Song et al. does not expressly include the calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (see e.g. col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (see e.g. col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the calibration step comprising calibration solution and obtaining a signal as taught by Han et al. in the method of Song et al. One of ordinary skill in the art would have been motivated to include the calibration step comprising calibration solution and obtaining a signal in the method of Song et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Song et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Song: col. 1, lines 8-10; Han col. 1, lines 16-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Song et al. and Han et al. because the calibration step is necessary to ensure the working order of the electrode.

33. Claims 83-101, 103-105, 107-109, and 111-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Patent 5,632,957) and Han et al. (US Patent 6,268,161 B1).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the*

*electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Heller et al. disclose a self-addressable self-assembling microelectronic device that can carry out a variety of reactions in microformats (see e.g. Abstract; col. 4, lines 48-59; col. 5, lines 3-37). The reaction steps comprise transporting the analytes to specific location wherein the analytes are effectively concentrated and reacted with the specific binding entity at the microlocation (refers to the instant claimed positioning step) (see e.g. col. 5, lines 4-8; col. 8, lines 18-25), and detecting the analyte by the detectable signal (refers to the instant claimed measuring step) (see e.g. col. 5, lines 32-37; col.9, lines 5-28; col. 19, lines 15-41). The method of Heller et al. further discloses the claimed method step of controlling a potential difference between two of the electrodes (see e.g. col. 7, lines 3-11; col. 8, line 53 to line 9; col. 9, lines 21-28). The microelectronic device comprises a substrate supporting an array of electronically addressable microlocations (see e.g. col. 7, line 66 to col. 8, lines 4; fig. 2A) and contact pads (refers to instant claim 100) (see e.g. col. 9, lines 52-64; fig. 3). The microlocations comprise an electrode layer, a permeation layer, and an attachment layer (see e.g. col. 8, lines 1-17; fig. 2). The electrode layer comprises a metal layer such as gold (refers to the claimed single layer of conductive material) and an adhesive layer such as titanium between the metal layer and the silicon substrate (see e.g. col. 16, lines 30-41; col. 17, lines 11-21). The microlocations further discloses the claimed positioning of the electrodes of claim 105 wherein two of the electrodes extend about a periphery of another of the electrodes (see e.g. fig. 2B, and 3). The array is in an 8X8 format (refers to the instant claim 113) (see e.g. col. 9, lines 52-56; fig. 3).

The method of Heller et al. does not expressly include the calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (see e.g. col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (see e.g. col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to as taught by Han et al. in the method of Heller et al. One of ordinary skill in the art would have been motivated to include the calibration step comprising calibration solution and obtaining a signal in the method of Heller et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Heller et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Heller: col. 5, lines 4-8; Han col. 1, lines 16-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Heller et al. and Han et al. because the calibration step is necessary to ensure the working order of the electrode.

34. Claims 83-97, and 99-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buck, Jr. et al. (US Patent 6,294,062 B1; *filing date of 6/1/1998*) and Han et al. (US Patent 6,268,161 B1).

*The instant claim 83 recites the method of detecting the presence or measuring the quantity of a target analyte in a sample reagent. The method comprises the step of 1) positioning the sample reagent on a biosensor; 2) controlling a potential difference between two of the electrodes; 3) measuring an electrical signal from the biosensor so as to determine the presence*

*and/or quantity of the target analyte in the sample reagent. The biosensor includes electrically conductive electrodes positioned on a substrate, and each of the electrodes consisting of a single layer of an electrically conductive material.*

Buck, Jr. et al. teaches immunosensors based on direct electrochemical measurement of detectable species with microarray electrodes under bipotentiostatic control and the method of detecting biological analytes in a liquid sample using the immunosenors (see e.g. Abstract; col. 1, lines 60-62; col. 3, lines 43-61; col. 4, lines 11-24). The method comprises the claimed step of 1) positioning the sample reagent on a biosensor (see e.g. col. 4, lines 27-31; col. 6, lines 49-53); 2) controlling a potential difference between two of the electrodes (see e.g. col. 4, lines 35-41; col. 6, lines 59-67; col. 7, lines 3-10); 3) measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent (see e.g. col. 4, lines 41-50; col. 7, lines 1-2, and 11-15). The method of Buck, Jr. et al. further discloses the instant claimed method step of controlling the potential difference is between the reference electrode and the working electrode, and the application of the current is through the counter electrode (see e.g. col. 8, lines 51-61). The liquid sample is a biological fluid (refers to instant claims 85-86 and 103) (see e.g. col. 7, lines 27-36). The immunosensors comprises the electrode structure that includes a reference electrode, working electrode and an auxiliary electrode for current control (refers to instant claimed biosensor and instant claims 108-111) (see e.g. col. 43-61; col. 7, lines 65-66; col. 8, line 54-55). The electrode is on a silicon substrate with a layer of chromium, and comprise of gold (refers to instant claims 84, 87-92, 94, 96-97, 99, 101, and 112) (see e.g. col., lines 26-40). The electrode structure is formed on an inner surface of a chamber for receiving the liquid sample (refers to instant claim 93) (see e.g. col. 8, lines 41-45). The electrode structure also is in contact with conductors (refers to claim 100) (see e.g. col. 49-50).

Furthermore, the features of remaining dependent claims 102, 105, 107, and 113, i.e. electrode structure/dimensions and positioning, are either specifically described by the reference (see e.g. col. 8, lines 10-22), or constitute obvious variations in parameters which are routinely modified in the art, and which have not been described as critical to the practice of the invention.

The device and method of Buck, Jr. et al. differs from the presently claimed invention by failing to include the calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (see e.g. col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (see e.g. col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to as taught by Han et al. in the method of Buck, Jr. et al. One of ordinary skill in the art would have been motivated to include the calibration step comprising calibration solution and obtaining a signal in the method of Buck, Jr. et al. for the advantage of determining the performance of the electrode before the analysis of the sample since both Buck, Jr. et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Buck: col. 1, lines 60-62; Han col. 1, lines 16-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the method combination of Heller et al. and Han et al. because the calibration step is necessary to ensure the working order of the electrode. Thus the combination of Buck, Jr. et al. and Han et al. is obvious over the presently claimed invention.

***Response to Arguments***

35. Applicant's argument(s) directed to the rejection under 35 U.S.C. 112, first paragraph (new matter), for claim 102 have been fully considered but they are not persuasive for the following reasons.

Applicant argues that "*Figure 3, Figure 4 and Figure 5 each illustrate sensors where each of the electrodes has a different shape. Observation of these Figures allows one to conclude that Applicant possessed a sensor where the electrodes have a different shape*" and thus claim 102 that recites "*each of the electrodes has a different shape*" has support in the specification.

Applicant's arguments are not convincing since claimed limitation of "*each of the electrodes has a different shape*" of claim 102 has no support in the instant specification. Claim 83 recites the biosensor includes electrically conductive electrodes positioned on a substrate and claim 102, which depend on claim 83, recites wherein each of the electrodes has a different shape. It is interpreted that the electrodes on a 'single' substrate has different shape. Figure 3, Figure 4, and Figure 5 ***each*** illustrate that ***all*** the electrodes on a 'single' substrate have the same shape (emphasis added) wherein the shape of ***all*** the electrodes in Figure 3 and 5 are square and the shape of ***all*** the electrodes in Figure 4 is circular. Thus there is no support for the claimed limitation that "*each of the electrodes has a different shape*" on a substrate, i.e. a single substrate, and the rejection is maintain for new claim 102.

36. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Song et al. (US Patent 5,567,302) was considered but they are not persuasive for the following reasons.

Applicant contends that the method of Song et al. does not anticipate the method of the instant claim 83 because Song et al. does not teach the method step of controlling a potential difference between two electrodes positioned on a substrate. Thus the method of the instant claim 83 is not anticipated by the method of Song et al.

Applicant's arguments are not convincing since the method of Song et al. does anticipate the method of the instant claim 83. The method of Song et al. does teach the method step of controlling a potential difference between two electrodes positioned on a substrate (see e.g. col. 5, lines 53-56; col. 17, lines 21-52). Thus the method of Song et al. does anticipate the method of the instant claim 83.

37. Applicant's argument directed to the rejection under 35 USC 102(b) as being anticipated by Heller et al. (US Patent 5,632,957) was considered but they are not persuasive for the following reasons.

Applicant alleges that the method of Heller et al. does not anticipate the method of the instant claim 83 because Heller et al. does not teach the method step of measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent. Thus the method of the instant claim 83 is not anticipated by the method of Heller et al.

Applicant's arguments are not convincing since the method of Heller et al. anticipate the method of the instant claim 83. First, the method of Heller et al. does teach the method step of measuring an electrical signal from the biosensor so as to determine the presence and/or quantity of the target analyte in the sample reagent (see e.g. col. 7, lines 3-11; col. 8, line 53 to line 9; col.

9, lines 21-28). Second, the instant claimed method recite wherein a surface on at least one of the electrodes is surface modified for anchoring molecules on the surface of claim 98, i.e. the 'measured' electrical signal from the biosensor is due to the 'binding' of the analyte to the surface of the biosensor. This would encompass the electronic hybrization analysis of Heller et al. (see e.g. col. 5, lines 32-34). Third, the comprising language of the instant claimed method does not exclude the additional optical method step of Heller et al. Therefore, the method of Heller et al. anticipates the method of the instant claim 83.

38. Since applicant did not present any argument(s) with regard to the rejection under 35 U.S.C. 103(a) as being unpatentable over Song et al. (US Patent 5,567,302) and Han et al. (US Patent 6,268,161 B1), the rejection is maintained for the newly added claims.

39. Since applicant did not present any argument(s) with regard to the rejection under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (US Patent 5,632,957) and Han et al. (US Patent 6,268,161 B1), the rejection is maintained for the newly added claims.

***Conclusion***

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
September 23, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER